For an item lost-in-transit,

- use the date of the sale,
- · the NDC and quantity of the item,
- the associate DEA number as the original sale record,
- a transaction code of X.

For a theft,

- report the date the theft occurred or was identified,
- the NDC and quantity of the item,
- a transaction code of T.
- The associate DEA number should be left blank.

For a destruction of a controlled substance (destroyed at your registered location),

- use the date the destruction occurred,
- the NDC and quantity of the item,
- a transaction code of Y
- the associate DEA number for the regional DEA office.

Product sent to a third-party for destruction are documented as a sale to the company. ARCOS records should be created through the invoicing process using transaction code S. If these activities occurred during a previous month, they should be reported as late transactions using the I code in the Action Indicator column.

ARCOS reportable items that are returned from an unknown source need to be documented as an addition to the inventory. This record is not generated by the system and needs to be created.

For an unsolicited return,

- use the date the product was received at the facility,
- the NDC and quantity of the item,
- a transaction code of V,
- the associate DEA number of UNKNOWN

The following are some sample lines from a report from the Distrack system., with a summary of what it means.

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THE MUNSTER COMPANY

ARCOS TRANSACTION EDIT REPORT DAILY TRANSACTIONS CALLED FOR BY SYC593 - END OF DAY PROCESSING PERIOD ENDING 3/19/98

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Field Name	Description	Definition	Function
YYMM	year and month	4 digit code to identify the year and month of the reporting period	reported to ARCOS to identify the reporting period
IDENT	transaction identifier	sequential number assigned by the reporting registrant to each transaction record	reported to ARCOS to identify the transaction
CDE	transaction code	single-character field which identifies each specific ARCOS-reportable activity. The entire list of available codes is on the next page.	reported to ARCOS to identify the activity
DATE	transaction date	the actual date on which the activity occurred	reported to ARCOS to identify the date of the activity
ITEM NUMBER	item number	number assigned by the company to a particular SKU	used by the division for research and identification purposes
NDC NUMBER	National Drug Code number	11-character code that identifies controlled substance products	reported to ARCOS to identify the item
DESCRIPTION	item description	description of the item including size, strength, and finished form	used by the division for research and identification purposes
ASSOC. ID NO.	associate identification number	number assigned by the company to the vendor or customer participating in the transaction	used by the division for research and identification purposes
ASSOC. DEA REG. NO.	associate DEA registration number	9-character field identifying the customer or supplier with which the transaction took place	reported to ARCOS to identify the other party in the transaction
BLANK FORM NO.	narcotic order form (DEA 222) number	9-character field for the number of the order form	reported to ARCOS for CII items
CORRECTION NUMBER	correction number	unique sequential number assigned by ARCOS to an erroneous transaction	reported to ARCOS for reprocessing a corrected transaction
DC	action indicator (formerly the delete indicator)	a single character field which initiates three different ARCOS data base operations	reported to ARCOS when deleting or revising previously submitted and accepted transactions, or when inserting unreported transactions from previous months.

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Field Name	Description	Definition	Function
QTY	quantity	numeric field containing the number of packages, weight, or volume being reported	reported to ARCOS to identify the quantity
BILL – ACCT #	Bill-to account number	customer number assigned by the company to the account that was invoiced for the product(s) in this transaction	used by the division for research and identification purposes
SHIP – ACCT #	Ship-to account number	customer number assigned by the company to the account that was delivered the product(s) in this transaction	used by the division for research and identification purposes
INVOICE NUMBER	invoice number	the number assigned to the invoice that reflects the sale to the customer	used by the division for research and identification purposes
INVOICE DATE	invoice date	the date the invoice was created. Usually matches the transaction date.	used by the division for research and identification purposes
MFG #	vendor number	number assigned to the vendor from whom the product was purchased	used by the division for research and identification purposes
PO#	purchase order number	number assigned to the order under which the product was purchased	used by the division for research and identification purposes
ADJ	inventory adjustment code	the code assigned to the adjustment to indicate the disposition of the inventory	used by the division for research and identification purposes
C/M#	credit memo number	the number assigned to the credit memo that reflects the return of the product from the customer	used by the division for research and identification purposes
SRC	source	identifies where the information came from that created the transaction record	used by the division for research and identification purposes

TRANSACTION CODES

(FROM PAGE 5-6 OF THE ARCOS REGISTRANT HANDBOOK)

INVENTORY TRANSACTION CODES

- 1 SCHEDULE CHANGE INVENTORY
- 3 YEAR-END INVENTORY
- 4 YEAR-END IN-PROCESS INVENTORY (MANUFACTURERS ONLY)
- 5 SPECIAL INVENTORY
- 8 NO YEAR-END INVENTORY

ACQUISITION TRANSACTION CODES (INCREASES TO INVENTORY)

- P PURCHASE OR RECEIPT
- R RETURN
- V UNSOLICITED RETURN
- W RECOVERED WASTE (MANUFACTURERS ONLY)
- M MANUFACTURED (MANUFACTURERS ONLY)
- G GOVERNMENT SUPPLIED
- L REVERSING (MANUFACTURERS ONLY)
- J RETURN OF SAMPLE TO INVENTORY (MANUFACTURERS ONLY)

DISPOSITION TRANSACTION CODES (DECREASES TO INVENTORY)

- S SALE, DISPOSITION, OR TRANSFER
- Y DESTROYED
- T THEFT
- N NONRECOVERABLE WASTE (MANUFACTURERS ONLY)
- U USED IN PRODUCTION (MANUFACTURERS ONLY)
- Z RECEIPT BY GOVERNMENT (SEIZURES, SAMPLES, ETC.)
- Q SAMPLING (MANUFACTURERS ONLY)
- K USED ON PREPARATIONS (MANUFACTURERS ONLY)

MISCELLANEOUS TRANSACTION CODES

- F REORDER DEA-333 FORMS
- X LOST IN TRANSIT
- 7 NO ARCOS ACTIVITY FOR THE CURRENT REPORTING PERIOD

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What To Do When A Report Is Received From ARCOS:

- Place the ARCOS template over the error report to separate the columns of information.
- 2. Identify the time period of the errors.
- 3. Retrieve the monthly report for that time period, to be used as reference.
- 4. Review the error code and the necessary correction action.
- 5. Determine if the error needs to be resubmitted. (Is it an ARCOS reportable item? Does the record reflect an actual transfer of product?)
- 6. Research any information pertinent to the type of error (invoice, receiver, credit memo, narcotic blank, etc.)
- 7. Create correction transactions in the ARCOS Maintenance Menu of the computer system. These transactions should be made in the current month's tape and not in the month of the original submission.
- 8. Make any necessary changes to the customer/vendor file or item file that could prevent future errors.

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EDIT ERRORS REPORT

DRUG ENFORCEMENT ADMINISTRATION DEPARTMENT OF JUSTICE ARCOS-2

DAILY TRANSACTIONS PROCESSING

ERROR REPORT

TRANSYLVANIA, PA 66613 1313 MOCKINGBIRD LANE THE MUNSTER COMPANY

ERRORS FOR CONTROL RECORD = = > RM1313666*043098M

E77 NDC NUMBER ISN'T ARCOS REPORTABLE. DON'T SUBMIT CORRECTED TRANSACTION. RM1313666S 5045800340500000192 RD01049599804757070428980000010200009804011749

CORRECTION NUMBER: 00000102

E48 ASSOCIATE REGISTRANT NUMBER IS NOT A VALID DEA REGISTRANT NUMBER RM1313666P 0000802580100000020 PA303798296215675504079800001030009804012347

CORRECTION NUMBER: 00000103

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Errors for Control Record

RM1313666 SUBMITTING REGISTRANT NUMBER

ASTERISK

043098

LAST DATE OF THE REPORTING PERIOD REPORT MEDIA (T=TAPE)
REPORTING FREQUENCY (M = MONTHLY)

LINE 1

RM1313666 REPORTING REGISTRANT NUMBER (DIVISION)

TRANSACTION CODE

50458003405 NATIONAL DRUG CODE (11 DIGITS)

00000192 QUANTITY (8 DIGITS)
RD0104959 ASSOCIATE REGISTRATION NI

RD0104959 ASSOCIATE REGISTRATION NUMBER (CUSTOMER OR VENDOR) 980475707 DEA ORDER FORM NUMBER (BLANK NUMBER, 9 DIGITS)

042898 TRANSACTION DATE

00000102 CORRECTION NUMBER
00009804 YEARMONTH OF REPORT

TRANSACTION IDENTIFIER

LINE 2

011749

8 ASSOCIATE REGISTRANT NUMBER IS NOT A VALID DEA RESGISTRANT NUMBER

LINE 3

CORRECTION NUMBER: 00000102

ERROR CODES

(FROM PAGE 7-5 OF THE ARCOS REGISTRANT HANDBOOK)

- E01 REPORTING REGISTRANT NUMBER DOESN'T MATCH THE ONE ON THE CONTROL RECORD
- E06 DELETE INDICATOR FIELD MUST BE BLANK OR MUST BE THE LETTERS "A", "D", OR "I"
- E07 DELETE INDICATOR FIELD MUST BE BLANK IF A CORRECTION NUMBER IS PRESENT
- E12 TRANSACTION DATE CONTAINS AN INVALID MONTH AND/OR AN INVALID DAY
- E13 TRANSACTION DATE MUST BE THE LAST DAY OF THE REPORT MONTH OR QUARTER
- E14 TRANSACTION CODE REQUIRED A YEAR-END DATE IN THE TRANSACTION DATE FIELD
- E15 TRANSACTION DATE IS LATER THAN THE RUN DATE OF THE ARCOS 2 EDIT PROGRAM
- E16 TRANSACTION DATE IS NOT WITHIN THE REPORTING REGISTRANTS REPORT PERIOD
- E17 TRANSACTION DATE ISN'T WITHIN THE 2 YEAR DATE RANGE OF THE ARCOS SYSTEM
- E21 CORRECTION NUMBER ENTERED IN INVALID. IT MUST BE NUMERIC
- E22 CORRECTION NUMBER IS NOT IN THE ERROR FILE
- E25 THE ARCOS EDIT STILL FOUND ERRORS ON THE CORRECTION TRANSACTION
- E28 DATA ENTERED IN THE QUANTITY FIELD IS INVALID. IT MUST BE NUMERIC.
- E31 THE UNIT VALUE ENTERED CANNOT BE USED WITH THE ENTERED NDC NUMBER
- E32 UNIT VALUE MUST BE BLANK, "D", "K", "1", "2", "3", "4", "5", "6"
- E35 STRENGTH MUST BE BLANK FOR BULK FINISHED OR 0001 TO 1000 FOR BULK RAW
- E36 STRENGTH IN INVALID. STRENGTH MUST BE BLANK OR NUMERIC
- E40 TRANSACTION CODE IS INVALID. SEE THE ARCOS MANUAL FOR VALID CODES.
- E41 TRANSACTION CODE IS RESERVED FOR DRUG MANUFACTURERS ONLY
- E42 TRANSACTION CODE REQUIRES ASSOCIATE REGISTRANT NUMBER TO BE BLANK
- E43 ASSOCIATE REGISTRANT NUMBER REQUIRES TRANSACTION CODE "Y", OR "G", OR "Z"
- E44 TRANSACTION CODE CONFLICTS WITH THE NDC NUMBER'S CSA SCHEDULE
- E45 TRANSACTION CODE REQUIRES AN ASSOCIATE REGISTRANT NUMBER ENTRY
- E46 ASSOCIATE REGISTRANT NUMBER IS INVALID FOR TRANSACTION CODE "Y/G/Z"
- E47 ASSOCIATE REGISTRANT NUMBER CAN'T EQUAL REPORTING REGISTRANT NUMBER
- E48 ASSOCIATE REGISTRANT NUMBER IS NOT A VALID DEA REGISTRANT NUMBER
- E49 ASSOCIATE REGISTRANT NUMBER IS INVALID FOR THE TRANSACTION CODE
- E52 THE ORDER FORM NUMBER HAS NOT BEEN CORRECTLY ENTERED
- E53 THE ORDER FORM NUMBER IS REQUIRED FOR SCHEDULE 1 & 2 DRUGS
- E60 TRANSACTION CODE 1 AN INVENTORY RECORD ALREADY EXISTS
- E61 TRANSACTION CODE 3 OR 8 YEAR-END INVENTORY AMOUNT ALREADY EXISTS
- E75 THE NDC NUMBER IS INVALID, IT CONTAINS ONE OR MORE SPACES
- E76 THE NDC NUMBER IS NOT IN THE DRUG FILE
- E77 NDC NUMBER ISN'T ARCOS REPORTABLE. DON'T SUBMIT CORRECTED TRANSACTION

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ARCOS Transaction Maintenance/AS400

Through the modified ARCOS Transaction Maintenance Menu, changes can be made not only to transactions from the current month, but also transactions to previous months. All of the maintenance must be done in the current reporting period to ensure that changes are added to the current month's tape.

Since transactions can now be from a variety of months (previous or current), the transaction ID will consist of the year/month (YYMM) and sequence number (Seq), as shown on the far left of each transaction.

Screen 1

From the ARCOS File Maintenance Menu, you must select the file type and enter the report reference date, as well as an access path. The file type can either be Monthly (M), Annual (A), or Special (S). A majority of the time, this selection will be M. The report reference date is the last date of the reporting period you have selected. For example, if you want to look at the records for May 1999, then you would enter M and 05311999. Through your selection of an access path, you make the determination of how the transactions are sorted. Entering a 'starting at' value can help to limit your search, but is not required. By leaving that field blank, the search will begin with the lowest value of your selected access path. The options for access path are:

- 1 = Corporate Item Number
- 2 = Blank Number
- 3 = NDC Number
- 4 = Customer Number
- 5 = Vendor Number
- 6 = DEA Number
- 7 = Sequence Number

Screen 2

After selecting the file type, the reference date, the access path and pressing enter, the next screen is displayed. The columns appearing on the screen are:

Sel = select transaction to update

Seq # = transaction ID

Trans Date = transaction date

Cd = transaction code

Dc = action indicator (only used for late, adjusted, and deleted transactions)

Cst/Vnd = customer or vendor number, depending on which access path was chosen

NDC/Item # = NDC or item number, depending on which access path was chosen

Quantity = transaction quantity

ASS Reg # = Associate registration number (DEA number of the other party involved in this transaction)

Blank # = order form number (required for CII transactions only)

If you choose a 'starting at' value in Screen 1, that equals a valid value for that access path, then that value will be highlighted in all of the transactions where it is included.

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You can scroll through transactions with a higher value for the access path, but in order to view transactions with a lower value, you must enter another value into the 'start at' field at the top of the screen and press F8. This 'start at' value is associated with the access path code selected on Screen 1. To select an alternative access path, press F12 to return to Screen 1.

To make a change to a transaction, enter '2' in the 'Sel' column and press enter. This will display the Change/Delete Current window. Changes can be made to any fields that are underlined. After completing the changes, press 'enter' and the transaction will be verified for accuracy and will be updated in the file. This function can be used for any transaction in the current batch including the current month's transactions, as well as any added, late or corrected transactions that have been entered.

To delete a transaction, enter '4' in the 'Sel' column and press 'enter'. This will display the Change/Delete Current window. No information can be entered into this pop-up window. Press <enter> to accept the delete. This function can be performed for any transaction that is displayed in the current batch that is not already deleted, this includes the current month's transactions, as well as any added, late or corrected transactions that have been entered. Deleted transactions will be displayed with an 'X' in the Dc column.

To add (current month) transactions, press (F6). This will display the Add Transaction pop-up window will appear requesting the required information. After completing the window, press <enter> and the transaction will be checked for accuracy and a transaction ID will be assigned. This add function can only be used for transactions that have occurred in the current month. Adding transactions from previous months is done using F14.

To add late (previous months) transactions, press (F14). This will display the Late Transaction popup window will appear requesting the required information. You must assign a transaction ID that includes the YYMM of the transaction and an original sequence number. The YYMM must be from a previous month. After completing the window, press <enter> and the transaction will be checked for accuracy and will be added to the batch. Late transactions will be noted with an 'I' in the Dc column. This function can only be used for transactions that have occurred in previous months.

To add corrected (DEA specified) transactions, press (F15). This will display the Correction Transaction pop-up window will appear requesting the required information. These transactions are identified on the ARCOS-2 Error Report. The correction transaction record must contain 1) all the fields that were correct on the original submission including the original transaction identifier, 2) the corrected field(s), and 3) the correction number. The YYMM must be from a previous month. After completing the window, press <enter> and the transaction will be checked for accuracy and will be added to the batch. Corrected transactions will be noted with a correction number under the Corr# column. This function can only be used for transactions that have been identified as errors by the DEA and must not have occurred in the current month.

To adjust (previous months) transactions, press (F20) This will display the Adjustment, Deletion pop-up window will appear requesting the required information. This is to correct mistakes on previously submitted transactions. Once these are identified, wait until the error report is received from ARCOS. If the transaction appears on the error report, a correction must be made using F15. If the transaction does not appear on the error report and was accepted by ARCOS, an adjustment must be made using F20. The first record created will be coded 'D' in the Dc column. You will then be

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prompted to adjust the transaction to reflect correct information. The second record will be coded 'A' in the Dc column.

To delete (previous months) transactions, press (F21) This will display the Delete, Previous pop-up window will appear requesting the required information. This is to delete transactions that were previously submitted but should not have been. The record will be coded D in the Dc column.

To unfold the screen, press (F10). This will expand a single transaction to two lines and include the customer name and the item description.

To select all transactions that meet a specified value in an access path, press (F7). This will put a '2' in the 'Sel' column. If the transactions span for more than one page, you must page forward to the last page of the highlighted transactions to select all of these transactions. If you press F7 without first paging forward, you will only select the specified transactions from the first page.

To mass update, press (F5). This will display the Mass Change pop-up window. From this window you have the option to change the NDC, DEA number or Blank number from the first transaction you selected to another value. It is recommended that mass changes only be made to the field that was selected in the access path.

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ARCOS File Maintenance - HP

Overview

In General:

The ARCOS File Maintenance screen allows the user to enter ARCOS File corrections. The screen was developed to replace the manual submission of corrections on ARCOS FORM 333 which the DEA will no longer accept from registrants who submit monthly reports electronically.

With the ARCOS file maintenance screen you have the ability to 1) make changes, additions and deletions to transactions prior to submission to ARCOS, 2) make adjustments, additions and deletions to transactions after acceptance by ARCOS, and 3) make corrections to transactions rejected by ARCOS.

Detailed Procedures

The ARCOS File Maintenance Screen is located on the **DEAMENUB**. To access **DEAMENUB**, log on to the live account and enter the following at the prompt: **MENU DEAMENUB**

Select option #11, ARCOS File Maintenance. This will take you to the ARCOS File Maintenance screen.

Note: Previous knowledge regarding the use of QUICK screens is needed to proceed with the following procedures.

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HODE:F ACTIO	ON :			DEA : RW0191318
ARCOS TRANSACTION MAINTENANCE			ELA THAVIVIOTO	
Trans llo.	Date Cd	Oc Order For	m N.D.C.∵No. O⊔antity	Assoc Reg# Correct#
$\begin{array}{cccc} 01 & & & \\ & & & \\ 02 & & & \\ & & & \\ \end{array}$	11/01/96 S	_ 960224487	00024027402 3	AN1471515
<u> </u>	11/01/96 S	_	00172564370 1	AN1471515
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	11/01/96 S		00074113403 10	AM1471515
<u> </u>	11/01/96 S		00044072802 1	BB3984413
	11/01/96 S	X	00785635001 1	BA3885160
066	11/01/96 S	-	000440727031	AT9562023
0.7 <u> </u>	11/01/96 S		000440728031	AT9562023
	11/01/96 S		604320457161	AT9562023
09 <u> </u>	11/01/96 S		51079042099 1	BC3621047
1010	11/01/96 S		50752029205 1	B\$4696590
<u> </u>	11/01/96 S		51079042020 1	AH2103454
1212	11/01/96 S		50474090201 1	BK3045211
1,313	11/01/96 5		50474090760 2	A\$3310315
14	11/01/96 S		50474090260 22	BN0963795
15	11/01/96 S	D 961420472	00008072901 1	AM5706861



This is a standard QUICK screen which allows the user to enter information needed tocorrect ARCOS transactions.

The Screen starts in find mode. The Screen will request the Trans ID to find or the user may hit enter to scan the file.

To change transactions

Changes to transactions may be made using the Find/Change command (F2). Once a transaction has been selected either by transaction identifier or by line number, the date field is erased for change. If no change is required, press <enter> and the next field will be erased and the date will reappear. Continue this process through the entire line, making change(s) where needed. When completed with the line, press F6 to update the file. The change function can be used for any transactions in the current batch including the current months transactions, as well as any transactions added from previous months.

To add (current month) transactions

Transactions for the current month can be added using the Add Trans Curr Mo command (F4). The system will assign the next available transaction number. You will be required to add the rest of the information, pressing <enter> to tab through the fields. When the record is complete, press F6 to update the file. The system will only accept a date within the current month. To add a transaction from a previous month, use F5.

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To add late (previous months) transactions

Transactions for previous months can be added using the Add Trans Prev Mo command (F5). You will be required to assign the transaction number using the next sequential number for that previous months batch. You will also be required to add the rest of the information for that transaction, pressing <enter> to tab through the fields. When the record is complete, press F6 to update the file. The system will require that the transaction date be from a previous month.

To delete transactions

Transactions from the current month can be deleted using the Delete Trans command (F7). You will be required to identify the transaction by transaction identifier or line number. The transaction will be coded with an 'X' and will be excluded from the tape. You must press F6 to update the file.

To delete (previous months) transactions

Transactions from previous months can be deleted by using a two step process of adding a previous months transaction and changing the code. First, add a transaction from a previous month using F5, keying in all of the required fields, pressing <enter> to tab through the fields. When the record is complete, you have the option of updating or changing it. To change the record, type the line number of the transaction (1) in the 'action' field, then change the 'I' in the Dc column to 'D'. Press F6 to update the file.

To adjust (previous months) transactions

Transactions from previous months can be adjusted by using a deletion from a previous month, in combination with a previous month add and a change of the code. First, add a transaction from a previous month using F5, keying in all of the information from the original transaction, pressing <enter> to tab through the fields. When the record is complete, change the code in the Dc column from 'I' to 'D'. Press F6 to update the file. A second transaction then needs to be added, containing all the fields that were correct on the original submission including the original transaction identifier, the corrected fields, and the correction number. When the record is complete, change the code in the DC column from 'I' to 'A'. Press F6 to update the file.

To add corrected (DEA specified) transactions

Transactions for correction can be done using a previous month add, including a correction number, then deleting the 'I' code. First, add a transaction from a previous month using F5, keying in all of the information from the original transaction, pressing <enter> to tab through the fields. Remember to include the correction number assigned to the transaction on the ARCOS Error Report. When the record is complete, remove the code in the Dc column. Press F6 to update the file.

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Screen Definitions

Field Name	Field Description
Trans No.	The ARCOS Transaction Identifier.
Date	The transaction date, format of MMDDYY. Do not enter slashes the screen with auto format the field.
Cd	Transaction Code. When in this field use Function key <f1> "HELP" for a list of acceptable transaction codes.</f1>
Dc	Delete Indicator. This field is used to mark ARCOS transactions for delete. When in this field use Function key <f1> "HELP" for a list of acceptable delete codes.</f1>
Order Form	The Order Form Number
N.D.C. No.	The National Drug Code number.
Quantity	The Quantity.
Assoc Reg#	The Associated DEA Registration Number.
Correct #	The ARCOS Correction Identifier.

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Screen Definitions

Function Ke	ey Label	Function Key Description
F1	HELP	This will give Help on the screen when used in the Action Box and will give help for a specific field when used in that field.
F2	Find / Change	This is used to find transaction by a Trans ID or to scan the file. After finding a transaction, enter the line number of the transaction to modify the data in a field.
F3	Find By Date	This function key will allow the user to retrieve all the transactions for a specific date.
F4	AddTrans Curr Mo.	This will allow the user to add a transaction for the current month.
F5	AddTrans Prev Mo.	The will allow the user to add a transaction for a prior month.
F6	Update	After changing, adding or deleting any transactions this function key MUST be used to permanently save the transaction.
F7	Delete Trans	This function key is used to mark a transaction for delete.
F8	Exit	This key will allow the user to exit from the screen.

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c 1391 Wilson Jones Company

DEA COMPLIANCE MANUAL

APPENDIX B

Test and Training Manual for Distribution Center Employees Handling Controlled Substances

TRAINING MANUAL FOR EMPLOYEES HANDLING CONTROLLED SUBSTANCES

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System Danci Aisidii Shii Keshunge	

Access Control
General Warehouse
Controlled Substances Area
Computer System
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Receiving 13
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INTRODUCTION

The Drug Enforcement Administration (DEA) is the primary federal law enforcement agency charged with combating drug abuse in this country. Established in 1973, it is a combination of the agencies formerly known as the Bureau of Narcotic and Dangerous Drugs, the Office for Drug Abuse Law Enforcement, the Office of National Narcotic Intelligence, and certain drug related elements of both the Bureau of Customs and the Office of Science and Technology. The intent of the amalgamation of agencies is to eliminate the piecemeal approach to the control of narcotics and dangerous drug and, by coordinating the effort, to control more effectively narcotic and dangerous drug activity and abuse.

Prior to this amalgamation of agencies, the laws on the control of drugs were collected and conformed into one piece of legislation, the Comprehensive Drug Abuse Protection Control Act of 1970 (the "Controlled Substance Act"). This act consolidated over 50 pieces of legislation that had been enacted in piecemeal fashion since 1914. The trust of this Controlled Substance Act is the improvement of the administration and regulation of manufacturing, distribution, and dispensing of controlled substances by establishing a "closed" system for legitimate drug handlers so that controlled drugs can be traced from their origin to their eventual user.

The act contains nine major control mechanisms that apply to the manufacture, purchase and distribution of substances subject to the act. They are:

- registration of handlers;
- record keeping requirements;
- manufacturing quotas;
- distribution restriction;
- limitations on imports and exports;
- conditions of storage of drugs;
- reports of transactions to the government; and
- criminal, civil and administrative penalties for violations.

Each of these mechanisms has a considerable impact upon the industry, especially the penalties and loss of registration provisions. Each violation of the act (which may be as little as misplacing one bottle of controlled substances) is punishable up to 15 years imprisonment and \$10,000 in fines. In addition, a relatively speedy administrative hearing can result in a finding of inadequate security. Such a finding could lead to loss of registration, effectively putting a company out of the controlled drugs distribution business. It has, therefore, become a cost justified good business practice to establish effective control measures in the first instance. DEA, like most other federal agencies, prefers voluntary rather than forced compliance.

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The DEA Diversion Control Program is responsible for implementing and maintaining controls over the distribution of legally produced controlled substances into the illegal market. The diversion control program operates through: periodic investigations to ensure that record keeping, reporting, and security requirements are being met; targeted investigations (for violative registrants); preregistration investigations; and organized system of destruction; manufacturing quotas; and drug scheduling (collection of abuse and diversion information). Periodic inspections are conducted as circumstances may require, based in part on the registrant's history of compliance and maintenance of effective controls to guard against the diversion of controlled substances.

This manual is intended as a resource to the Controlled Substance Act and Regulations. It is intended as a guide so that you can better understand DEA's function. Further, it is intended to help you learn to deal with the agency that has and tremendous impact on our business.

In addition to this manual, you should also have the following DEA publications available for ready reference:

Code of Federal Regulations 21. Food and Drugs Part 1300 to End – available from:

Superintendent of Documents U.S. Government Printing Office Washington, D.C. 20402 (202) 783-3238

ARCOS Reporting Manual - available from:

United States Department of Justice Drug Enforcement Administration ARCOS Unit, P.O. Box 27273 Central Station Washington, D.C. 20038-7273 (202) 307-8600

Note: The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level.

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INVENTORY

There are specific regulations with regards to inventory. DEA requires a biennial inventory, and a year-end ARCOS inventory. As company policy, periodic inventories are recommended. Unless otherwise specified, the general requirements pertain to each type of inventory. Refer to Procedural Security for additional information on the Physical Verification of Controlled Substances.

Biennial

(21 CFR 1304.11 (c))

Frequency. Every two years, the wholesaler is required to take a physical inventory of all controlled drug stocks on hand.

When. The regular biennial inventory date is every two years from the date the wholesaler initially became registered to distribute controlled substances. Thus, for all firms who were provisionally registered on May 1, 1971, the biennial inventory date is May 1st every odd year. For any firm registered after May 1, 1971, or which has been issued a new registration since May 1, 1971, the regular inventory date is two years from the initial date of registration, e.g., Firm A which first became registered on August 21, 1974, has a regular biennial inventory date of August 21 every even year. The wholesaler may take the inventory within four days of the inventory date if he/she notifies the DEA special agent in charge in advance.

Cardinal Health has received authorized from DEA for all Cardinal Health locations to conduct biennial inventories on December 31 of even numbered years.

Year-End ARCOS

(21 CFR 1304.33 (b))

Frequency. Every year, the wholesaler is required to take a physical inventory of all reportable controlled substances on hand.

When. The inventory should report the stock on hand as of the close of business on December 31st.

Reporting. A report of the inventory shall be filed with the ARCOS Unit of the Drug Enforcement Administration by January 15th of the following year.

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